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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/674,702	09/30/2003	Gail K. Buehler	MCP5017	4561

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/674,702	BUEHLER ET AL.	
	Examiner	Art Unit	
	Layla Soroush	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 December 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17 and 19-22* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Office Action is in response to the Applicant's reply filed December 27, 2006 to the restriction requirement made on November 29, 2006.

Applicant's election of a species for a) active agent-an anti-histamine active (loratadine); b) thickener- xanthan gum with starch; c) nucleation inhibitor -PVP; d) amino polycarboxylic acid compound of Formula I or II -EDTA, and e) surfactant - sorbitan oleate ester in the reply filed on December 27, 2006 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The restriction requirement is deemed proper and made FINAL.

Claim 18 is withdrawn from further consideration pursuant to 37 C.F.R. 1.142(b), as being drawn to non-elected subject matter. The claims corresponding to the elected subject matter are 1-17 and 19-22 and are herein acted on the merits.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-16, 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (US Pat. No. 5,980,882) in view of Gowan, Jr. (US 5374659 A) and Oshlack et al. (US 5,356,467).

Eichman teaches drug resin complexes stabilized by chelating agents. "The particle size of a resin can differ between two resins." The chelating agent is preferably EDTA (amino polycarboxylic acid compound). Additionally, the reference teaches drug resin complex comprising a solvating agent and a diffusion barrier coating. Solvating agents may be used in the process to prevent the resin particles from breaking and to aid in the application of coatings. The drug-resin complex may be coated with a film-forming polymer. Coatings can be of any film-forming material with diffusion barrier properties.

Eichman fails to teach the specific active agent, thickener, and nucleation inhibitor claimed.

Oshlack et al. teaches a stable aqueous dispersion comprising one or more pore-formers. Pore formers control the release of active agents and upon exposure to fluids in the environment, the pore-formers are, e.g., dissolved and channels and pores are formed that fill with the environmental fluids. Examples of pore formers include starch, modified starch, starch derivatives, gums, inclusive of xanthan gum (thickener), and cross-linked polyvinylpyrrolidone (nucleation inhibitor). Active agents include antihistamines. The aqueous dispersions of the present invention preferably have a pH from about 4 to about 6. When the pH of an aqueous dispersion is above pH 6 or below

pH 4, the dispersion has been found to become unstable. The particle size is from about 0.01 to about 10um in the aqueous dispersion.

Gowan, Jr. teaches an aqueous pharmaceutical suspension composition comprising an insoluble pharmaceutical active, a suspension stabilizing effective amount of xanthan gum, pregelatinized starch and polyoxyethylene sorbitan monooleate.

The pregelatinized starch component used in combination with xanthan gum in accordance with the present invention has been found to provide superior storage stable and homogeneously dispersed suspensions of water insoluble pharmaceutical actives. Additionally, once the sorbitan oleate ester is wetted by the aqueous phase, the surfactant provides stability by what is known as steric stabilization. The non-polar group adsorbs onto the non-wetting hydrophobic surface of the solid phase and the polar end extends into the aqueous phase. This dual absorption allows the suspended particles to be surrounded by water molecules and incorporated into the aqueous solution. In accordance with the present invention the suspension is stabilized by a mixture of suspension stabilizing effective amounts of xanthan gum, preglatinized starch and polyoxyethylene sorbitan monooleate.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Eichman, Gowan, Jr., and Oshlack et al. The motivation to combine the teachings is because Eichman teaches (1) drug resin particles complexed with chelating agent comprising solvating agents and a diffusion barrier coating Oshlack et al. teaches

(2) one or more specific diffusion barrier coatings (pore formers) inclusive of starch, modified starch, starch derivatives xanthan gum (thickener), and cross-linked polyvinylpyrrolidone (nucleation inhibitor), and Gowan, Jr. teaches (3) the suspension of an insoluble pharmaceutical active is stabilized by a mixture of suspension stabilizing effective amounts of xanthan gum, preglatinized starch and polyoxyethylene sorbitan monooleate. A skilled artisan would have reasonable expectation of effectively producing a composition with diffusion barrier properties (pore-formers) which (1) control the release of active agents and (2) stabilize an insoluble pharmaceutical active in a suspension.

Eichman, Gowan, Jr., and Oshlack et al. meet all elemental steps of the instant claims and the compositions created thereof. Since the compositions prepared by Eichman and Oshlack et al. meets all elemental components of the instantly prepared composition, they would obviously exhibit the same properties as recited in claims 8-10. 2 and 21

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eichman (US Pat. No. 5,980,882) in view of Gowan, Jr. (US 5374659 A) and Oshlack et al. (US 5,356,467), as applied to claims 1-16, 19-22 above, and further in view of Gergely et al. (US 5834019 A).

Eichman, Gowan, Jr., and Oshlack et al. are discussed above.

Eichman, Gowan, Jr., and Oshlack et al. fail to teach the specific Loratadine compound recited in claim 17.

Gergely et al. teaches Loratadine is virtually completely water-insoluble and has a very strongly hydrophobic character. It is thus extremely poorly wettable and therefore difficult to suspend. Its fine particles furthermore have the tendency to form a film on the water surface, to creep up the glass wall to a pronounced extent and to adhere relatively strongly there.

It would have been obvious to one of ordinary skill in the art to combine the teachings of Eichman and Oshlack et al. with Adnderson et al. The motivation to combine the teachings is because Eichman teaches (1) drug resin particles, Oshlack et al. teaches (2) active agents including antihistamines in the said composition, (3) Gowan, Jr. teaches the suspension of an insoluble pharmaceutical active. A skilled artisan would have reasonable expectation of effectively stabilizing loratadine (antihistamine) a water-insoluble pharmaceutical active.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

S. [illegible]